Substances. Letter to diethylene glycol butyl ether manufacturers and users. 1984.

(17) USEPA. (May 1). Behavior/distribution of diethylene glycol butyl ether in the environment. Intraagency memorandum from R. Kinerson to P. Price, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, DC 20460. 1948.

(18) USEPA. (November 20) U.S. Environmental Protection Agency. ENPART analysis of DGBA, TGD, and oleylamine. Interagency memorandum to Test Rules Development Branch, Office of Toxic Substances, U.S. Environmental Protection Agency, Washington, DC 20460. 1984.

(19) USEPA. U.S. Environmental Protection Agency. TSCA Chemical Substances Inventory (public portion). Washington, DC 20460. 1984.

(20) Volpe, P. (Nov. 18), National Association of Printing Ink Manufacturers, Harrison, NY. Personal communication with A. Engelkemeir, Dynamac Corp., 11140 Rockville Pike, Rockville, MD 20852. 1983.

(21) Woebkenberg, J. (Dec 8). SCM Glidden Corp., 6151 Sprague Rd., Strongsville, OH 44136. Personal Communication with A. Engelkemeir, Dynamac Corp., 11140 Rockville Pike, Rockville, MD 20852. 1983.

This record includes basic information considered by the Agency in developing this notice and is available for public inspection and copying in the OPTS Reading Room, Rm. E-107, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays (401 M St., SW., Washington, D.C. 20460). The Agency will supplement the record periodically with additional relevant information received.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous material, Chemicals.

(Sec. 4, Pub. L. 94-469, 90 Stat. 2003; 15 U.S.C. 2601)

Dated: November 8, 1984.

William D. Ruckelshaus,

Administrator.

[FR Doc. 84-30229 Filed 11-18-84; 8:45 am]
BILLING CODE 6560-50-M.

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40 CFR Part 799

[OPTS-42061; FRL 2690-5]

Oleylamine; Proposed Test Rule

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The EPA is proposing that manufacturers and processors of oleyamine (9-octadecenylamine, ODA) be required, under the Toxic Substances Control Act, to perform testing for (1) developmental toxicity, (2) 90-day dermal subchronic toxicity which will include neurobehavioral observations, emphasis on reproductive system histopathology, and a dermal absorption determination, and (3) mutagenicity using a tiered scheme with triggers to oncogenicity testing. This proposed rule is in response to the Interagency Testing Committee's designation of ODA for priority consideration of health effects testing.

DATES: Submit written comments on or before January 18, 1985. Make requests to submit oral comments by January 3, 1985. If requests are made to submit oral comments, EPA will hold a public meeting on February 4, 1985, on this rule in Washington, D.C. For further information on arranging to speak at the meeting see Unit VI of this preamble.

ADDRESS: Submit written comments in triplicate identified by the document control number (OPTS-42061) to: TSCA Public Information Office (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, Rm. E-108, 401 M St. SW., Washington, D.C. 20460.

A public version of the administrative record supporting this action (with any confidential business information deleted) is available for inspection at the above address from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS-799), Rm. E-543, 401 M St. SW., Washington, D.C. 20460, Toll Free: (800-424-9065), In Washington, D.C.: (554-1404), Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION: EPA is issuing a proposed test rule under section 4(a) of TSCA in response to the Interagency Testing Committee's designation of oleylamine for health effects testing consideration.

I. Introduction

Section 4(e) of TSCA (Pub. L. 94-469, 90 Stat. 2003 *et seq.*; 15 U.S.C. 2601 *et seq.*) established an Interagency Testing Committee (ITC) to recommend to EPA a list of chemicals to be considered for testing under section 4(a) of the Act.

The ITC designated oleylamine (9-octadecenylamine, or ODA, CAS #112-90-3) for priority consideration in its 13th Report and submitted it to EPA on November 25, 1983. The submission was published in the Federal Register of December 14, 1983 (48 FR 55674). (Hereafter "ODA" will refer to the substance, 9-octadecenylamine, and the term "oleylamine" will refer to commerical fatty amine mixtures containing 65 to 76 percent ODA.) The ITC recommended that ODA be considered for a staged testing program, beginning with toxicokinetics and then testing for mutagenicity and teratogenicity if percutaneous absorption is demonstrated. This notice of proposed rulemaking serves as EPA's response to the recommendations of the ITC for ODA. The bases of these recommendations were as follows: production of 4.5 to 5.5 million pounds per year, estimated occupational exposure of 3,155 workers, positive data from dietary and intraperitoneal teratogenicity studies, and lack of sufficient data to characterize the effects of concern for ODA.

Under section 4(a) of TSCA, the Administrator shall by rule require testing of a chemical substance or mixture to develop approrpriate test data if the Agency finds that:

(A)(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data; or

(B)(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data.

In making a section 4(a)(1)(A)(i) finding, EPA considers both exposure and toxicity information to make the finding that the chemical may present an unreasonable risk. For the first finding under section 4(a)(1)(B), EPA considers only production, exposure and release information to determine if there is substantial production and significant or substantial exposure or substantial release. For the second finding under both sections 4(a)(1)(A) and 4(a)(1)(B), EPA examines toxicity and fate studies to determine if existing information is adequate to reasonably determine or predict the effects of human exposure or environmental release of the chemical. In making the third finding that testing is

necessary, EPA considers whether any ongoing testing will satisfy the information needs for the chemical and whether testing which the Agency might require would be capable of developing the necessary information.

EPA's approach to determining when these findings are appropriately made is described in detail in EPA's first and second proposed test rules as published in the Federal Register of July 18, 1980 (45 FR 48528) and June 5, 1981 (46 FR 30300). The section 4(a)(1)(A) findings are discussed in 45 FR 48528 and 46 FR 30300 and the section 4(a)(1)(B) findings are discussed in 46 FR 30300.

In evaluating the ITC's testing recommendations for ODA, EPA considered all available relevant information including the following: Information presented in the ITC's report recommending testing consideration; production volume, use, exposure, and release information reported by manufacturers of ODA under the TSCA section 8(a) Preliminary Assessment Information Rule (40 CFR Part 712); unpublished health and safety studies submitted by manufacturers and processors of ODA under the TSCA section 8(d) Health and Safety Data Reporting Rule (40 CFR Part 716); and other published and unpublished data available to the Agency.

II. Proposed Rule

On the basis of its evaluation as described in this proposed rule and the technical support document (Ref. 1), EPA is proposing for ODA oral developmental toxicity [1] testing, a tiered mutagenicity testing scheme with the capacity to trigger oncogenicity testing (see further explanation in section VI–E of Ref. 1; see also II.H of this notice), and a 90-day dermal subchronic toxicity test. The 90-day test is to include neurobehavioral observations, emphasis on reproductive system histopathology and a dermal absorption determination. The Agency is proposing this testing under the authority of section 4(a)(1)(B) of TSCA; the developmental toxicity testing is also being proposed under section 4(a)(1)(A).

A. Profile

ODA (CAS No. 112–90–3) is a yellow liquid with an ammoniacal ordor. Typical fatty amine mixtures (67 percent ODA) have a boiling range of 275–344 °C at 760 mm HG and a specific gravity of 0.819 at 38 °C. ODA's solubility in water is estimated to be 0.5×10^{-3} mg/l or less at 20 °C, its estimated vapor pressure is 0.5×10^{-4} mm Hg at 10 °C and its estimated log P (octanol-water partition coefficient) ranges from 7.5 to 8.1.

$CH_3(CH_2)_7Ch=CH(CH_2)_7CH_2NH_2$

9=octadecenylamine (ODA)

Industry estimates of production of oleylamine in 1982 range from 5.5 to 6.5 million pounds, and the U.S. International Trade Commission (USITC) reports 1982 oleylamine production to be 4.952 million pounds. Both of these production figures are for fatty amine mixtures called oleylamine by the producers. EPA estimates that the ODA contained in all the fatty amine mixtures produced in 1982 amounts to between 18 and 29 million pounds. ODA is produced by six firms: Akzo Chemie America; Witco Chemcial Corp.; Jetco Chemicals, Inc.; Sherex Chemical Company, Inc.; Borg-Warner Corp.; and Tomah Products, Inc. Production is conducted at nine sites. Akzo uses a continuous reaction process and the others use closed batch reactors. Akzo produces over fifty percent of the total U.S. production. ODA's major use in which human exposure is probable is as an additive to petroleum lubricants or as an intermediate for such additives. It is also used as a collector agent in ore flotation, in asphalt preparation, in a concrete mold release agent and in the manufacture of paper, paperboard, and glues. For a more detailed discussion of properties, productions, uses and exposure of oleylamine and other ODA-containing mixtures, see the oleylamine support document available from the TSCA Assistance Office.

B. Findings

EPA is basing its proposed testing of ODA on the authority of sections 4(a)(1)(A) and 4(a)(1)(B) of TSCA.

1. The section 4(a)(1)(A) findings for developmental effects are as follows:

a. EPA finds that the manufacture, processing, and use of ODA may present an unreasonable risk of injury to human health due to developmental toxicity because (1) available animal studies suggest that ODA may cause such effects and (2) in excess of 2.8 million individuals are potentially exposed to ODA as a result of its manufacture, processing, and use. The primary route of human entry is thought to be dermal absorption of ODA-containing lubricants.

b. EPA also finds that there are insufficient animal and human data to reasonably determine or predict the developmental toxicity of ODA. The finding of "may present an unreasonable risk" of adverse developmental effects is based in part on a study (Ref. 2) in which pregnant mice (4-5 per dose group) were exposed to single doses of ODA either by intraperitonal (i.p.) injection (200, 400, 600, or 1,600 mg/kg) or orally (200, 800, or 3,200 mg/kg). Maternal lethality was produced in the two highest i.p. groups and the highest oral group. Dose-related increases occurred in percentages of fetal resorption (all groups) and skeletal malformations (400 and 800 mg/kg i.p. groups). Dose-related decreases occurred in fetal body weights in all i.p. groups.

These data are not adequate to characterize the potential developmental toxicity of ODA. The study was too limited in design, and analysis and reporting of results provided too little information to adequately assess ODA's potential as a developmental hazard.

Rabbit and rat studies (Refs. 3 through 7) also support a finding of a potential unreasonable risk of adverse developmental effects. In each of these studies pregnant rabbits or rats (14–22 per dose group) were exposed orally to a 1:1 mixture of ODA hydrofluoride and cetylamine hydrofluoride (1.2, 6.0, and 30 mg/kg/day) during all or part of the gestation period until sacrifice or day 21 postnatally. Teratological, fertility, reproductive, and perinatal and postnatal observations were made. Compared to controls, there were increased intrauterine deaths at the majority of dose levels in the majority of groups, and ossification variations and malformations at the higher three dose levels in approximately one-half of the test groups.

These data are also not adequate to characterize the potential adverse developmental effects of ODA. The effects were not always observed at levels of statistical significance; there was evidence of inconsistent observations from study to study; and it cannot be determined to what extent the adverse effects observed may have been influenced by the presence of the hydrofluoride or cetylamine constituents.

c. EPA finds that additional developmental effects testing of ODA is necessary to develop adequate data to evaluate reasonably the developmental risks posed by exposure to ODA.

2. The section 4(a)(1)(B) findings are as follows:

a. EPA finds that ODA is produced in substantial quantities. Production of oleylamine was reported by the USITC to be 4.952 million pounds in 1982. Production estimates for ODA, however, range to 29 million pounds for 1982

[1] The Agency has concluded that the term "developmental toxicity" is more appropriate than the term "teratogenicity" and therefore it will be used in place of the term "teratogenicity". For a more complete discussion see 49 FR 39810 (October 10, 1984).

when the ODA portion of captive production as well as production of all commercial OSA-containing substances is taken into account.

b. EPA also finds that there may be substantial human exposure to ODA. On the basis of the National Occupational Hazard Survey conducted in 1972–1974, eight occupations in six industries involving an estimated 3,155 workers were found to be subject to exposure to ODA-containing products of various kinds. The major human exposure route is thought to be dermal absorption from ODA-containing lubricants handled by mechanics and workers in other machine-related occupations. For 1984, the Bureau of Labor Statistics has identified eight mechanic and other machine-related occupations which involve approximately 2.8 million workers.

c. EPA finds that there are insufficient data available to reasonably determine or predict the effects of this exposure in the areas of developmental toxicity, mutagenicity, oncogenicity, subchronic toxicity, neurobehavioral effects, reproductive histopathology and dermal absorption. EPA, therefore, finds that testing of ODA is necessary to develop such data.

The analysis on which the above findings are based is presented in the oleylamine support document which is a part of this rulemaking record (Ref. 1). EPA is proposing limited initial testing of ODA rather than the full range of testing often used by the Agency under section 4(a)(1)(B) of TSCA.

In cases of section 4(a)(1)(B) findings for chemicals with widespread exposure at moderate to high concentration levels, such as 1,1,1-trichloroethane, EPA has generally followed a policy that data from a broad range of tests are necessary to reasonably determine or predict the risks that may be presented by the chemical's manufacture, processing, distribution in commerce, use, and disposal. Such tests include mutagenicity, acute toxicity, acute dermal irritation/corrosion, acute eye irritation/corrosion, skin sensitization, oncogenicity, chronic effects, reproductive effects, teratogenicity, and neurotoxicity (Federal Register, June 5, 1981, 46 FR 30302). EPA would require testing for all such effects for which adequate data are not available. However, in cases where EPA finds that there is substantial production and that a substantial number of persons may be exposed, but that such exposure is typically to low levels of a chemical, EPA makes a case-by-case judgment as to what testing should be required. The use of a screening approach seems appropriate for low-level exposure to chemicals for which little or no toxicity data exist. Adverse effects would only be expected at these exposure levels for highly toxic chemicals. Screening tests should enable EPA to identify significant toxicities of the chemical and determine what, if any, further testing is necessary.

The low-level exposure situation appears to apply to ODA. Specifically, the Agency notes that use of ODA is not expected to expand to types of products other than the current use in lubricants and related products, and that product concentrations are limited to 1 percent or less of oleylamine. Thus, in conjunction with existing data on acute effects and the developmental toxicity testing proposed above, EPA believes that for ODA a screening approach consisting of mutagenicity tests and a 90-day dermal subchronic test with reproductive system histopathology and neurobehavioral observations is appropriate. The dermal route of administration reflects the expected human exposure pattern. The added reproductive system histopathology in the subchronic test will screen for reproductive toxicity. Similarly, a functional observation battery will screen for neurotoxic effects, and mutagenicity testing will screen for oncogenic potential. In all cases, positive results could lead to a determination that more testing should be done; negative results would provide reasonable assurance of little or no potential risk.

From data for structurally similar chemicals, EPA believes that some dermal absorption of ODA will occur (see section VI.A of Support Document). Therefore, the Agency is not following the ITC's recommendation of an initial toxicokinetics study with testing for specific health effects if percutaneous absorption is demonstrated. However, EPA is proposing that a dermal absorption determination be conducted as part of the 90-day subchronic study to provide data relevent to interpreting the oral test for developmental effects.

The ITC recommendations and EPA's proposed tests are summarized below:

TESTING FOR OLEYLAMINE

Test	ITC recommendation	EPA proposal
Toxicokinetics	X	X[a]
Genotoxicity	Conditional[b]	X
Teratogenicity	Conditional[b]	X (Developmental toxicity)
Oncogenicity		Conditional[c]
90-Day dermal subchronic toxicity.		X
Neurobehavioral observations.		X[a]
Reproductive system histopathology.		X[a]

[a] Included in 90-day subchronic testing.
[b] Depends on toxicokinetics results.
[c] Depends on genotoxicity results.

EPA is not proposing an oncogenicity bioassay based on the section 4(a)(1)(B) finding because EPA considers the required mutagenicity tests as an appropriate first tier for oncogenicity. However, EPA finds that if certain of the required mutagenicity tests produce positive results, this will be sufficient to indicate that ODA may present an unreasonable risk of oncogenic effects. In such circumstances, EPA finds that without data from a 2-year bioassay there will be insufficient data to predict oncogenicity, and testing will be necessary to develop oncogenicity data.

The scheme for triggering to higher-tier mutagenicity and oncogenicity testing is similar to that proposed for the cresols (48 FR 31812, July 11, 1983) and the C9 aromatic hydrocarbons (48 FR 23088, May 23, 1983). The tier testing scheme proposed for ODA is described in detail in unit V.1.D. of the oleylamine support document which is part of this rule-making record. The Agency has received and evaluated comments on these notices and is reviewing its policy on the use of triggers between mutagenicity tests and from mutagenicity tests to oncogenicity testing. EPA will publish the results of this review in the near future. The Agency does not request further comment in this area, but those wishing to comment may do so.

C. Test Substance

ODA is routinely manufactured, sold, and used industrially as a fatty-amine mixture. Laboratory grade ODA (97 percent pure) is used in much smaller quantities. EPA is proposing that the test substance be the purest commercial form of ODA in a suitable vehicle. Comments are requested in unit II.H of this preamble on whether the commercial or laboratory grade ODA would be the most appropriate test substance. The vehicle should be one such as mineral oil for which there are historical toxicological data and which will not interfere with test results.

D. Persons Required to Test

Section 4(b)(3)(B) of TSCA specifies that the activities for which the Administrator makes section 4(a) findings (manufacturing, processing,

distribution in commerce, use and/or disposal) determine who bears the responsibility for testing. Manufacturers are required to test if the findings are based on manufacturing ("manufacture" is defined in section 3(7) of TSCA to include "import"). Processors are required to test if the findings are based on processing. Both manufacturers and processors are required to test if the exposures giving rise to the findings occur during use, distribution, or disposal. Because EPA has found that the manufacture, processing and use of ODA may present an unreasonable risk of developmental effects and that the use of ODA-containing substances may give rise to substantial human exposure (unit II.B), EPA is proposing that persons who manufacture or process, or who intend to manufacture or process substances containing this chemical at any time from the effective date of this test rule to the end of the reimbursement period, be subject to the rule. The end of the reimbursement period will be 5 years, or an amount of time equal to that which was required to develop data if more than 5 years, after the submission of the last final report required under the final test rule. As discussed in unit II.E, EPA expects that manufacturers will conduct testing and that processors will ordinarily be exempted from testing.

Because TSCA contains provisions to avoid duplicative testing, not every person subject to this rule must individually conduct testing. Section 4(b)(3)(A) of TSCA provides that EPA may permit two or more manufacturers or processors who are subject to the rule to designate one such person or a qualified third person to conduct the tests and submit data on their behalf. Section 4(c) provides that any person required to test may apply to EPA for an exemption from that requirement.

E. Test Rule Development and Exemptions

Test rule development for ODA will be conducted as a two-phase process under the regulations in 40 CFR Part 790 (49 FR 39774, October 10, 1984). In this proposed phase I rule, EPA is proposing that specific testing be required for ODA. This phase of the rulemaking will allow the public to comment on the decision to require testing and the specific types of tests to be required. Phase II will begin after promulgation of the final phase I rule. In phase II, EPA will receive proposed study plans for the specific test requirements adopted in the phase I rule. EPA will make those study plans available for public comment. After comment, the Agency will adopt the study plans, as proposed or modified, as specific test standards for the tests required by the phase I rule. Persons who submit the study plans will be obligated to perform the tests in accordance with the test standards adopted.

EPA's final regulations for the issuance of exemptions from two-phase test rule testing requirements are in 40 CFR Part 790 (49 FR 39774, October 10, 1984). In accordance with these rules, any manufacturer or processor subject to a phase I test rule may submit an application to EPA for an exemption from submitting study plans and from conducting any or all of the tests required under such a rule. If manufacturers perform all the required testing, processors will be granted exemptions automatically without having to file applications.

EPA is not proposing to require the submission of equivalence data as a condition for exemption from the proposed testing for ODA. As noted in unit II.C, EPA has specified that the highest purity ODA commercially available be used for testing.

F. Reporting Requirements

EPA is proposing that all data developed under this rule be developed and reported in accordance with the final TSCA Good Laboratory Practice (GLP) Standards (40 CFR Part 792).

EPA is required by TSCA section 4(b)(1)(C) to specify the time period during which persons subject to a test rule must submit test data. These deadlines will be established in the phase II rulemaking in which study plans are approved.

TSCA section 14(b)(1)(A)(ii) governs Agency disclosure of all test data submitted pursuant to section 4 of TSCA. Upon receipt of data required by this rule, the Agency will publish a notice of receipt in the Federal Register as required by section 4(d).

G. Enforcement Provisions

Section 15(1) of TSCA makes it unlawful for any person to fail or refuse to comply with any rule or order issued under section 4. Section 15(3) of TSCA makes it unlawful for any person to fail or refuse to (1) establish or maintain records, (2) submit reports, notices, or other information, or (3) permit access to or copying of records required by the Act or any regulation or rule issued under TSCA. The Agency considers that failure to comply with any aspect of a section 4 rule or the submission of invalid data would be violations of section 15 of TSCA.

Additionally, TSCA section 15(4) makes it unlawful for any person to fail or refuse to permit entry or inspection as required by section 11. Section 11 applies to any "establishment, facility, or other premises in which chemical substances or mixtures are manufactured, processed, stored, or held before or after their distribution in commerce * * *." The Agency considers a testing facility to be a place where the chemical is held or stored, and therefore subject to inspection. Laboratory audits/inspections will be conducted periodically in accordance with the authority and procedures outlined in TSCA section 11 by authorized representatives of the EPA for the purpose of determining compliance with this rule. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to TSCA Good Laboratory Practice Standards and the test standards adopted in the phase II rule.

EPA's authority to inspect a testing facility also derives from section 4(b)(1) of TSCA, which directs EPA to promulgate standards for the development of test data. These standards are defined in section 3(12)(B) of TSCA to include those requirements necessary to assure that data developed under testing rules are reliable and adequate, and such other requirements as are necessary to provide such assurance. The Agency maintains that laboratory inspections are necessary to provide this assurance.

Violators of TSCA are subject to criminal and civil liability. Persons who submit materially misleading or false information in connection with the requirement of any provision of this rule may be subject to penalties which may be calculated as if they had never submitted their data. Under the penalty provision of section 16 of TSCA, any person who violates section 15 could be subject to a civil penalty of up to $25,000 per day for each violation. Each day of operation in violation may constitute a separate violation. This provision would be applicable primarily to manufacturers or processors that fail to submit a letter of intent or an exemption request and that continue manufacturing or processing after the deadlines for such submissions. Knowing or willful violations could lead to the imposition of criminal penalties of up to $25,000 for each day of violation and imprisonment for up to 1 year. In determining the amount of penalty, EPA will take into account the seriousness of the violation and the degree of culpability of the violator as well as all the other factors

listed in section 16. Other remedies are available to EPA under section 17 of TSCA, such as seeking an injunction to restrain violations of TSCA section 4.

Individuals, as well as corporations, could be subject to enforcement actions. Sections 15 and 16 of TSCA apply to "any person" who violates various provisions of TSCA. EPA may, at its discretion, proceed against individuals as well as companies. In particular, this includes individuals who report false information or who cause it to be reported. In addition, the submission of false, fictitious, or fraudulent statements is a violation under 18 U.S.C. 1001.

H. Issues

1. EPA believes that manufacturers of any ODA-containing substances should be subject to this proposed rule. However, some such substances contain very small quantities of ODA. Of the 22.2 million pounds of primary fatty amine mixtures produced in the U.S. in 1982 (Ref. 10), 6 percent or 1.3 million pounds contained less than 20 percent ODA; some contained as little as 1 percent. The Agency requests comment from interested parties as to whether there is an ODA concentration below which a manufacturer of such a substance need not be required to perform testing.

2. EPA finds that ODA is produced in substantial quantities and that a substantial number of people are potentially exposed to it, but that exposures are to products containing low concentrations of ODA. The Agency requests comment from interested parties on the issue of whether the reproductive toxicity and neurotoxicity screening tests proposed for ODA are adequate, given the low expected exposure levels of ODA.

3. The ITC recommended an initial toxicokinetics study on ODA with mutagenicity and teratogenicity studies if percutaneous absorption is demonstrated. EPA proposes health studies initially, with dermal absorption as a part of a 90-day subchronic test. Because the Agency's analysis suggests that some dermal absorption is likely (Ref. 1), EPA believes health effects testing would still be necessary to determine the significance of whatever absorption did take place. ODA producers recommend an initial toxicokinetics study to determine ODA absorption (Ref. 9). They feel that a low degree of absorption would eliminate any need for further tests. The Agency requests comment from other interested parties on the issue of whether dermal toxicokinetics studies should precede other testing of ODA, and if so, how a suitable level of dermal absorption might be selected to serve as a trigger for additional health effects testing.

4. EPA has proposed that the route of administration of ODA be dermal in a 90-day dermal subchronic test and a 2-year oncogenicity test (if such testing is indicated by prior mutagenicity tests) because the primary route of human exposure is dermal absorption. However, certain difficulties are encountered when the dermal route of exposure is used. For example, due to scratching or licking by the test animal, it may be difficult to determine the actual amount of test substance available for absorption. The Agency requests comment from interested parties as to whether the dermal or some other route of administration of ODA should be used in the 90-day subchronic or oncogenicity tests.

5. Although the primary route of human exposure to ODA is by dermal absorption, EPA has proposed developmental toxicity testing by the oral route. This is based on the fact that the available data base on developmental toxicity testing by the dermal absorption route is extremely small whereas that for oral testing is considerable. For this reason EPA believes the advantage of being better able to interpret data obtained by the oral route outweighs that of the expected human exposure (dermal) route. The Agency requests comment from interested parties as to whether the oral route is the most appropriate for animal studies of developmental toxicity in this case.

6. EPA has proposed that reproductive system histopathology studies be conducted in conjunction with a 90-day dermal subchronic test with ODA. Organs to be studied are vagina, uterus, ovaries, testes, epididymus, seminal vesicles, and prostate. The Agency requests comment as to the adequacy of these studies as indicators of potential reproductive system effects.

7. EPA is proposing that the test substance be the purest commercial form of ODA. The purest ODA generally used in commerce consists of fatty amine mixtures containing 65 to 76 percent ODA. A laboratory grade is also available which is 97 percent ODA. In general, the Agency prefers that the purest available form of a chemical be used for testing, in order that interpretation of test data will not be complicated by the presence of substantial quantities of other substances. For many substances, a large fraction of the expected exposure is to a high purity material. In the case of ODA, however, only a very small number of laboratory workers may be exposed to 97 percent ODA. The Agency requests comment on which substance should be tested in this instance.

III. Economic Analysis of Proposed Rule

To evaluate the potential economic impact of test rules, EPA has adopted a two-stage approach. All candidates for test rules go through a Level I analysis; this analysis consists of evaluating each chemical, or chemical group on four principal market characteristics: (1) Price sensitivity of demand, (2) industry cost characteristics, (3) industry structure, and (4) market expectations. The results of the Level I analysis for ODA, along with a consideration of the cost of the required tests, indicate that the potential for an adverse economic impact is very low; therefore, a Level II analysis, which quantifies the potential for adverse economic impact, was not needed for ODA.

Total testing costs for the testing in this proposed rule for ODA are estimated to range from $391,593 to $1,174,628 depending on the need to perform higher-tiered mutagenicity and oncogenicity testing. The annualized costs range is $101,468 to $304,365 per year based upon specific test requirements. On the basis of an estimated total ODA production volume of 18 to 29 million pounds per year, the cost of testing represents approximately 0.6 to 1.7 cents per pound of ODA contained in the various amine products. These costs represent between 0.01 to as much as 1 percent of amine product value depending on ODA content.

The potential for significant adverse economic effects due to this test rule is small. The market characteristics of ODA-containing products indicate that the potential for adverse economic impact as a result of the small additional product cost increases is low. This suggests that the ecomonic impact would be minimal.

For a more complete and thorough discussion of the methodology used to conduct the economic analysis of this test rule see Ref. 8. A copy of this document is available in the public record for this rulemaking, docket number [OPTS–42061].

IV. Availability of Test Facilities and Personnel

Section 4(b)(1) requires EPA to consider "the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule." Therefore, EPA conducted a study to assess the availability of test facilities and personnel to handle the additional demand for testing services created by section 4 test rules and test programs

negotiated with industry in place of rulemaking. Copies of the study, "Chemical Testing Industry: Profile of Toxicological Testing", October 1981, can be obtained through the National Technical Information Service (Publication No. PB 82-140773).

On the basis of this study, the Agency believes that there will be available test facilities and personnel to perform the testing required in this proposed rule.

V. Guidelines and Study Plans

The following guidelines/study plans and other relevant sources of information cited in this proposed test rulemaking are available from the following sources:

1. National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, (703-487-4650).

NTIS publication No.	Title	Price
PB 83-153918	Pesticide Assessment Guidelines	$16.00
PB 84-233295	New and Revised Health Effects Test Guidelines	25.00

2. Hemisphere Publishing Corp., 1025 Vermont Avenue, NW., Washington, D.C. 20095, (202-783-3958).

Dermatotoxicology, 2nd Ed., 1983 Editors: F. F. Marzulli and H. I. Maibach.....$64.50

3. OECD Publications and Information Center, Suite 120, 1750 Pennsylvania Avenue, NW., Washington, D.C. 20006, (202-724-1857).

OECD Guidelines for the Testing of Chemicals..... $60.00

VI. Public Meetings

If persons indicate to EPA that they wish to present comments on this proposed rule to EPA officials who are directly responsible for developing the rule and supporting analyses, EPA will hold a public meeting on February 4, 1985, in Washington, D.C. This meeting will be held after the deadline for submission of written comments, so that issues raised in the written comments can be discussed by EPA and the public commenters. Information on the exact time and place of the meeting will be available from the TSCA Assistance Office. Toll Free: (800-424-9065). In Washington, D.C.: (554-1404). Outside the U.S.A.: (Operator-202-554-1404).

Persons who wish to attend or present comments at the meeting should call the TSCA Assistance Office by January 3, 1985. While the meeting will be open to the public, active participation will be limited to those persons who have arranged to present comments and to designated EPA participants. Attendees should call the TSCA Assistance Office before making travel plans because the meeting will not be held if members of the public do not indicate they wish to make oral comments.

Should a meeting be held, the Agency will transcribe the meeting and include the written transcript in the public record. Participants are invited, but not required, to submit copies of their statements prior to or on the day of the meeting. All such written materials will become part of EPA's record for this rulemaking.

VII. Judicial Review

When this proposed rule is promulgated, judicial review may be available under section 19 of TSCA in the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which the person seeking review resides or has its principal place of business. To provide all interested persons an equal opportunity to file a timely petition for judicial review and to avoid so called "races to the courthouse," EPA intends to promulgate this rule for purposes of judicial review two weeks after publishing the final rule in the Federal Register. The effective date will be calculated from the promulgation date.

VIII. Public Record

EPA has established a public record for this rulemaking, docket number [OPTS-42061]. This record includes the basic information considered by the Agency in developing this proposal, and appropriate Federal Register notices. The agency will supplement the record with additional information as it is received.

The record includes the following information:

A. Supporting Documentation

(1) Federal Register notices pertaining to this rule consisting of:

(a) Notice containing the designation of ODA to the priority list (48 FR 55674, December 14, 1983) and all comments on ODA received in response to that notice.

(b) Notice of proposed test rule on ODA.

(c) Notice of final rule on EPA's TSCA good laboratory practice standards (48 FR 53922, November 29, 1983).

(d) Notice of final rule on test rule development and exemption procedures (49 FR 39774, October 10, 1984).

(e) Notice of final rule on 1,1,1-trichloroethane establishing Part 799 General Provisions (49 FR 39810, October 10, 1984).

(f) Notice of final rule on data reimbursement policy and procedures (48 FR 31786, July 11, 1983).

(2) Support Documents: consisting of:

(a) ODA technical support document.

(b) Economic analysis support document.

(3) Minutes of informal meetings.

(4) Communications before proposal consisting of:

(a) Written public and intra-agency or interagency memoranda and comments.

(b) Summaries of telephone conversations.

(c) Summaries of meetings.

(d) Reports—published and unpublished factual materials, including contractor's reports.

B. References

(1) USEPA. U.S. Environmenal Protection Agency. Assessment of testing needs: oleylamine (9-octadecenylamine) support document. Washington, D.C. Office of Toxic Substances. 1984.

(2) Eifinger, F.F. and Koehler, F. "Comparative Teratological Studies with Organic Fluoride Compounds, their Bases and Amines." Dtsch. zahnaerztl. Z. 32:861-866. (In German; English translation) 1977.

(3) Bio/dynamics Inc. A segment III perinatal and postnatal study of amine fluoride 335/242 in rats. Project No. 72R-819. Philadelphia, PA: Menley and James Laboratories. 1973.

(4) Bio/dynamics Inc. Amine fluoride 335/242 segment II rabbit teratology study. Project No. 72R-818. Philadelphia, PA: Menley and James Laboratories. 1973.

(5) Bio/dynamics Inc. A segment I rat fertility study of amine fluoride 335/242. Project No. 72R-817. Philadelphia, PA: Menley & James Laboratories. 1973.

(6) Bio/dynamics Inc. A segment II rat teratology study of amine fluoride 335/242. Project No. 72R-820. Philadelphia, PA: Menley and James Laboratories. 1973.

(7) Bio/dynamics Inc. Segment II rat teratology study of amine fluoride 335/242 (repeat of previous study). Project No. 73R-880. Philadelphia, PA: Menley and James Laboratories. 1973.

(8) USEPA. U.S. Environmental Protection Agency. Economic Impact Analysis of Proposed Test Rule for 9-Octadecenylamine. Washington, D.C. Office of Toxic Substances. 1984.

(9) USEPA. U.S. Environmenal Protection Agency report of meeting with representatives of Akzo Chemie America and Chemical Manufacturers Association. May 9, 1984.

(10) USITC. International Trade Commission. Synthetic Organic Chemicals. U.S. production and sales, 1982. Washington, D.C.: U.S. Government Printing Office, USITC pub. 1422. 1983.

Confidential business information (CBI), while part of the record, is not available for public review. A public version of the record, from which CBI has been deleted, is available for inspection in the OPTS Reading Room, Rm. E-107, 401 M St. SW., Washington, D.C., from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

IX. Other Regulatory Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is major and therefore subject to the requirement of a Regulatory Impact Analysis. According to section 1, definition (b) "major rule" means any regulation that is likely to result in: (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. This test rule is not major because it does not meet any of the criteria set forth in section 1(b) of the Order. First, the estimated annual cost of all the testing proposed for ODA is $115,048 to $344,625 per year over the testing and reimbursement period. Second, because the cost of the required testing will be distributed over a large production volume, the rule will have only very minor effects on users' prices for this chemical, even if all test costs are passed on. Finally, taking into account the nature of the market for this substance, the low level of costs involved, and the expected nature of the mechanisms for sharing the costs of the required testing, EPA concludes that there will be no significant adverse economic effects of any type as a result of this rule.

This proposed regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291. Any comments received from OMB are included in the Public Record for this rulemaking.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), (15 U.S.C. 601 *et seq.*, Pub. L. 96–354, September 19, 1980), EPA is certifying that this test rule, if promulated, will not have a significant impact on a substantial number of small entities for the following reasons:

1. All six manufacturers are large businesses or subsidiaries of large businesses. There are no small manufacturers of this chemical.

2. Small processors are not expected to perform testing themselves, or participate in the organization of the testing efforts.

3. Small processors will experience only very minor costs if any in securing exemption from testing requirements and are unlikely to be affected by reimbursement requirements.

4. The magnitude of the unit costs of testing is relatively low, or less than two cents per pound in the upper bound case. Thus, any testing costs passed on to small processors through price increases will be small.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) has approved the information collection requirements contained in the proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq*, and has assigned OMB control number 2070—0033. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB, marked Attention: Desk Officer for EPA. The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Part 799

Testing, Environmental protection, Hazardous material, Chemicals.

(Sec. 4, Pub. L. 94–469, 90 Stat. 2006; 15 U.S.C. 2603)

Dated: November 8, 1984.

William D. Ruckelshaus,

Administrator.

PART 799—[AMENDED]

Therefore, it is proposed that 40 CFR Part 799 be amended by adding § 799.3300 to read as follows:

§ 799.3300 Oleylamine.

(a) *Identification of test substance.* (1) 9-Octadecenylamine (hereafter ODA) (CAS No. 112–90–3) shall be tested in accordance with this part.

(2) The ODA test substance shall be the purest commercial form: Laboratory grade (97 percent ODA). The vehicle shall be one such as mineral oil for which there are adequate historical toxicological data and which will not interfere in the test results.

(b) *Persons required to submit study plans, conduct tests and submit data.* All persons who manufacture or process substances containing ODA from the effective date of the final rule to the end of the reimbursement period shall submit letters of intent to test, exemption applications, and study plans and shall conduct tests and submit data as specified in this section and Part 790 of this chapter. (Information collection requirements approved by the Office of Management and Budget under control number 2070–0033.)

(c) *Health effects testing*—(1) *Developmental effects*—(i) *Required testing.* An oral developmental toxicity test shall be conducted with ODA in two mammalian species, preferably rat and rabbit.

(ii) *Study plans.* For guidance in preparing study plans, the New and Revised Health Effects Test Guidelines, published by NTIS (PB 84–233295) should be consulted. Additional guidance may be obtained from the Pesticide Assessment Guidelines, published by NTIS (PB 83–153916).

(2) *Mutagenic effects—Chromosomal aberrations—(i) Required testing.* (A) An *in vitro* cytogenetics test shall be conducted with ODA.

(B) An *in vivo* cytogenetics test shall be conducted with ODA if the *in vitro* cytogenetics test conducted pursuant to paragraph (c)(2)(i)(A) of this section produces a negative result.

(C) A dominant lethal assay shall be conducted with ODA if either the *in vitro* or *in vivo* cytogenetics test conducted pursuant to paragraph (c)(2)(i) (A) or (B) of this section produces a positive result.

(D) A heritable translocation assay shall be conducted with ODA if the dominant lethal assay conducted pursuant to paragraph (c)(2)(i)(C) of this section produces a positive result.

(ii) *Study plans.* For guidance in preparing study plans, the New and Revised Health Effects Test Guidelines, published by NTIS (PB 84–233295), should be consulted. Additional guidance may be obtained from the Pesticide Assessment Guidelines, published by NTIS (PB 83–153916).

(3) *Mutagenic effects—Gene Mutations*—(i) *Required testing.* (A) A *Salmonella typhimurium* mammalian microsomal reverse mutation assay (hereinafter "Ames assay") shall be conducted with ODA.

(B) A gene mutation in somatic cells assay shall be conducted with ODA if the Ames assay conducted pursuant to paragraph (c)(3)(i)(A) of this section produces a negative result.

(C) A sex-linked recessive lethal test in *Drosophila melanogaster* shall be conducted for ODA if either the Ames assay or the gene mutation in somatic cells assay conducted pursuant to paragraph (c)(3)(i) (A) or (B) of this section produces a positive result.

(D) A mouse specific locus test shall be conducted for ODA if the sex-linked recessive lethal test in *Drosophila melanogaster* conducted pursuant to paragraph (c)(3)(i)(C) of this section produces a positive result.

(ii) *Study plans.* For guidance in preparing study plans, the New and Revised Health Effects Test Guidelines, published by NTIS (PB 84–233295), should be consulted. Additional

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guidance may be obtained from the Pesticide Assessment Guidelines, published by NTIS (PB 83-153916).

(4) *Oncogenicity*—(i) *Required testing.* A 2-year, dermal oncogenicity bioassay shall be conducted with ODA if positive results are obtained in any of the following mutagenic effect tests conducted pursuant to paragraph (c) (2) or (3) of this section:

(A) The gene mutation assay in mammalian cells.

(B) The sex-linked recessive lethal gene mutation assay in *Drosophila melanogaster*.

(C) The *in vitro* cytogenetics assay, or

(D) the *in vivo* cytogenetics assay.

(ii) *Study plans.* For guidance in preparing study plans, the New and Revised Health Effects Test Guidelines, published by the NTIS (PB 84-233295), should be consulted. Additional guidance may be obtained from the Organization for Economic Cooperation and Development (OECD) "Guidelines for the Testing of Chemicals" as adopted by the OECD Council on May 12, 1981, and the Pesticide Assessment Guidelines, published by NTIS (PB 83-153916).

(5) *Subchronic effects*—(i) *Required testing.* A 90-day dermal subchronic toxicity test shall be conducted with ODA. Neurobehavioral observations, reproductive system histopathology, and a dermal absorption determination shall be included.

(ii) *Study plans.* For guidance in preparing study plans, the New and Revised Health Effects Test Guidelines, published by the NTIS (PB 84-233295), and *Dermatotoxicology,* 2nd Ed., published by the Hemisphere Publishing Corp. should be consulted. Additional guidance may be obtained from the Pesticide Guidelines, published by NTIS (PB 83-153916).

(d) *Availability of guidelines.* The guidelines cited in this proposed rule are available from:

(1) National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161, (703-487-4650).

NTIS publication	Title
PB 83-153916	Pesticide Assessment Guidelines
PB 84-233295	New and Revised Health Effects Test Guidelines

(2) Hemisphere Publishing Corp., 1025 Vermont Ave, NW., Washington, D.C. 20095, (202-783-3958).
Dermatotoxicology, 2nd Ed., 1983
Editors: F. F. Marzulli and H. I. Maibach.

(3) OECD Publications and Information Center, Suite 120, 1750 Pennsylvania Ave., NW., Washington, D.C. 20006, (202-724-1857). OECD Guidelines for the Testing of Chemicals.

[FR Doc. 84-30222 Filed 11-16-84; 8:45 am]
BILLING CODE 6560-50-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 95

Automatic Data Processing Equipment and Services; Conditions for Federal Financial Participation

AGENCY: Office of the Secretary, HHS.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: In September 1978, Health and Human Services (HHS) published a regulation containing requirements that State and local governments must observe to claim Federal reimbursement for the costs of automatic data processing (ADP) equipment and services. The regulations are applicable to certain public assistance programs under the Social Security Act. The regulations were modified in February 1980 to implement certain changes.

These regulations change requirements for the claiming of Federal matching funds for the acquisition of automatic data processing (ADP) equipment and services in the administration of public assistance programs under the Social Security Act titles I, IV, X, XIV, XVI (AABD), XIX and XX.

The change modifies the regulation to conform to recent legislative changes and raises the HHS prior approval threshold for most State and local government acquisitions. The purpose of the change is to:

—Simplify and make these regulations consistent, to the maximum extent possible, with those regulations that govern availability of FFP at the enhanced matching rate for computerized systems that support programs under title IV-A, IV-D and XIX of the Social Security Act;

—Allow States more flexibility in implementing small systems; and

—Reduce paperwork.

DATES: Comments must be received by January 18, 1985. If we receive substantive comments, HHS will reissue the NPRM at a later date. We will consider comments submitted in response to the present effort to update Office of Management and Budget Circular A-102, to the extent that such comments relate to provisions of these proposed regulations.

ADDRESSES: Send written comments to: Joseph F. Costa, Director, Office of Public and State Data Systems, OMAS, Hubert H. Humphrey Building Room 514-E, 200 Independence Ave., SW., Washington, D.C. 20201.

FOR FURTHER INFORMATION CONTACT: Joseph F. Costa (202) 245-7488.

SUPPLEMENTARY INFORMATION: HHS, then Health, Education, and Welfare (HEW), published final regulations "Automatic Data Processing Equipment and Services—Conditions for Federal Financial Participation", Subpart F of 45 CFR Part 95 in the Federal Register, page 44851, on September 29, 1978. These regulations required State and local governments to obtain prior written approval by the Department for the acquisition of ADP equipment or ADP services when the acquisition costs exceeded $25,000. These regulations were modified by a rule change published in the Federal Register, page 10794, on February 19, 1980, to raise the prior approval threshold to $100,000 for acquisitions costing that amount or more in Federal and State funds over a twelve-month period and to $200,000 in Federal and State funds for the total acquisition. The change also required States to submit a brief prior notice of acquisition for ADP equipment and services that cost $25,000 to $100,000 over a twelve-month period.

In analyzing State requests made since the 1980 regulation change, HHS found that State requests for acquisitions costing between $100,000 and $200,000 represent 9.9 percent of the total number of requests but only 1.4 percent of the dollar amount requested. Additionally, HHS found that States had submitted only 109 prior notices during the three-year period. Therefore, HHS is raising the prior approval threshold to $200,000 for acquisitions costing that amount or more in Federal and State funds over a twelve-month period and to $300,000 in Federal and State funds for the total acquisition; and is eliminating the prior notice requirement, thus reducing paperwork requirements. The changes also modify the regulation to conform to recent legislative changes in administration of some Social Security Act programs and to clarify the regulatory language.

Specifics of the changes are:

1. The Adoption Assistance and Child Welfare Act of 1980 (Pub. L. 96-272, June 17, 1980) amended title IV of the Social Security Act by adding Part E—Federal Payments for Foster Care and Adoption Assistance. We are adding title IV-E to the applicable list of programs covered under this regulation. This is based on